UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,112	04/17/2004	Reuben Matalon	P71641US0	9858

136 7590 08/01/2008

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,112	MATALON, REUBEN	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 35-56* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 41-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-33, 35-40, 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed April 15, 2008 has been received and entered into present application. Claim 34 was canceled and claim 56 was added by applicant. Thus claims 1-16, 41-55 remain withdrawn, and thus 17-33, 35-40, and 56 are currently under examination.

Applicants' arguments, filed April 15, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant objected to the examiner's citation of a reference that was not in English, with no translation provided. The examiner apologizes for not providing an English Translation at the time, that was the result of trying to expedite the examination process and due to the fact that without any knowledge of the German language, the examiner was confident that the applicant and/or attorneys would be able to determine the percentages taught. The English language translation of DE 4037447 is provided at this time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-33, and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Wachtel et al. (DE 4037447 A1, translation provided), already of record, for the reasons set forth at pages 3-6 of previous office action dated October 15, 2007, of which reasons are herein incorporated by reference.

Claims 17-33 and 35-36 were rejected in the previous office action as being anticipated by Wachtel et al. Applicant asserts that the examiner misread Wachtel et al. and that the +/- 10% is a 10% of each value variation rather than a 10% total variation. While that is one possible interpretation of the art, it is not the only one and there is no reason that it must be the way the applicant asserts. Wachtel et al. clearly states the percentages cited in the previous office action on page 10 (of the translation) and on page 11, Wachtel et al. states that the proportions of lysine, isoleucine, leucine, valine, and tyrosine can deviate by up to +/-10% and that the proportions for the remaining amino acids can deviate up to +/- 20% from the mentioned value (page 11). This can clearly be taken to mean a 10 % (or 20%) fluctuation in the proportions and thus the previous interpretation of values such as 14.5% [4.5-24.5%] is appropriate and within the scope of the teaching by Wachtel et al.

Applicant's argument is that this cannot be an appropriate interpretation because of amino acids such as histidine, which is claimed at 5% (+/- 20%) which could be less

than 0% and "obviously makes no sense". This is not a persuasive argument, because one of ordinary skill in the art, including the Wachtel et al. would know that there cannot be percentages less than 0% and thus 0% is the lower limit of any range. Wachtel et al. would assume this to be obvious to anyone reading their patent and would not feel the need to further state this conclusion. This is standard practice in the art, such as is the practice of having totals of less than or more than 100%. Given the ranges cited, the total percentage of amino acids listed on page 10 could be more than or less than 100% but it would be assumed that one of ordinary skill in the art would appreciate that the total must equal 100% and therefore is not necessary to explicitly state this. Thus the mere fact that the +/- 20% range could lead to negative values is not reason enough to assume that the 10% value is only in relationship to the percentage claimed (for example only 1.45% in the case of Lysine or 1.6% in the case of tyrosine). Thus the previous calculations for a 500mg tablet, based on the teaches of Wachtel et al. are correct and claims 17-33, and 35-36 are anticipated by Wachtel et al. for the reasons discussed in the previous office action dated October 15, 2007.

This argument is not deemed persuasive and thus the rejection of claims 17-33, and 35-36 is **maintained.**

Claim Rejections - 35 USC § 102 (New grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Wachtel et al. (DE 4037447 A1, translation provided), already of record, for the reasons set forth at pages 3-6 of previous office action dated October 15, 2007, of which reasons are herein incorporated by reference.

Applicant added claim 56, which is merely the same claim as the original claim 33 which was rejected under 35 USC 102(b) as anticipated by Wachtel et al. in the previous office action dated October 15, 2007. For the reasons discussed in the previous rejection, and the reasons discussed above for claims 16-33, and 35-36, claim 56 is anticipated by Wachtel et al. **This new grounds of rejection is necessitated by the addition of claim 56.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wachtel et al. (DE 4037447 A1) in view of Ghadimi et al. (US 3,822,465), in further view

of Nakaki et al. (Beneficial Circulatory Effect of L-arginine) each already of record, for the reasons set forth at pages 7-9 of previous office action dated October 15, 2007, of which reasons are herein incorporated by reference.

Claims 37-40 were rejected over Wachtel et al. in view of Ghadimi et al. in further view of Nakaki et al. Applicant has maintained that this rejection does not provide a *prima facie* obviousness because it would not have been obvious to adjust both the amount of amino acids and add arginine. This adjusting the amount of amino acids is based on applicant's argument that Wachtel et al. does not teach the amounts of amino acids claimed, based on the above mentioned argument that the 10% deviation is really 1.45% (in the case of lysine). This argument is not found persuasive, and thus this is not an issue for a prima facie obviousness. As already established in the previous office action, but reiterated here for clarity, there is motivation to add arginine and add it in the quantities claimed. Wachtel et al. teaches the composition claimed, except that they do not teach arginine in their composition. Their composition is however, designed for treatment of Phenylketonuria (PKU). Ghadimi et al. taught almost all of the same amino acids as Wachtel et al., with the addition of arginine and the amount of arginine encompasses that claimed in the instant invention. Nakaki et al. teaches that arginine is a necessary amino acid, which infants cannot synthesize, and that for infants with PKU, arginine is a necessary ingredient. Thus there is a clear and obvious motivation to add arginine to the PKU therapy of Wachtel et al., in order to treat infants with PKU. Ghadimi would provide a known in the art range of arginine to use, and some experimentation for dosages is routine in the art, but the starting range of Ghadimi et al.

which encompasses the claimed amount, would provide an excellent starting point for one of ordinary skill in the art making the obvious motivation of adding arginine to the method of Wachtel et al. **Thus there is a clear prima facie obviousness case for the addition of arginine and claims 37-40 are unpatentable of Wachtel et al. in view of Ghadimi et al. in further view of Nakaki et al.**

This argument is not deemed persuasive and thus the rejection of claims 37-40 is **maintained.**

Conclusion

Rejections of claims 17-33, 35-40, and 56 are deemed proper and are **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614